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510(k) Summary Summary of Safety and Effectiveness

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Proprietary Name	LifeScan SureStep®Pro blood glucose monitoring system
Common name	Blood glucose monitor
Classification name	75CGA: glucose oxidase, glucose test system

Device description

The SureStepPro blood glucose monitoring system consists of a glucose reagent test strip, a reflectance photometer, and quality control solutions. A data management system for hospital tracking of patient and quality control information will also be available.

Intended Use

The LifeScan SureStepPro blood glucose monitoring system is intended for quantitative measurement of glucose in a sample of whole blood. It can be used in a clinical setting to measure glucose in arterial, venous, and capillary samples in both adults and neonates. It can also be used by lay persons for capillary blood glucose monitoring in the home.

Substantial Equivalence

The LifeScan SureStepPro blood glucose monitoring system is substantially equivalent to the currently marketed LifeScan SureStep® Blood Glucose Monitoring System and the LifeScan ONE TOUCH® II *Hospital* Blood Glucose Monitoring System.